

1 HONORABLE RICARDO S. MARTINEZ
2
3
4
5
6
7
8

9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

IN RE ATOSSA GENETICS, INC.
SECURITIES LITIGATION

CASE NO: 13-cv-1836-RSM

SECOND AMENDED CLASS ACTION
COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Miko Levi, Bandar Almosa, and Gregory Harrison (“Lead Plaintiffs”) and Paul Asher (together with Lead Plaintiffs, “Plaintiffs”), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their Second Amended Complaint against Defendants, allege the following based upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Atossa Genetics, Inc. (“Atossa” or the “Company”), analysts’ reports and advisories

CERTIFICATE OF SERVICE
CASE NO: 13-cv-1836-RSM

Zwerling, Schachter & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel.: (206) 223-2053

1 about the Company, and information readily obtainable on the Internet.¹ Plaintiffs believe that
 2 further evidentiary support will exist for the allegations set forth herein after a reasonable
 3 opportunity for discovery.

4 **NATURE OF THE ACTION**

5 1. This is a federal securities class action on behalf of a class consisting of all persons
 6 and entities, other than Defendants, who purchased or otherwise acquired Atossa shares between
 7 December 20, 2012 and October 4, 2013, both dates inclusive (the “Class Period”), seeking to
 8 recover damages caused by Defendants’ violations of the federal securities laws and to pursue
 9 remedies under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”)
 10 and Rule 10b-5 promulgated thereunder, against the Company and its Chairman, President, and
 11 Chief Executive Officer, Steven C. Quay.

12 2. Defendants misrepresented that its sole product, the ForeCYTE Breast Health Test
 13 (“ForeCYTE Test”), had received all required clearances from the FDA for sale to the public. In
 14 fact, the ForeCYTE Test had not received the required FDA clearances. The FDA informed
 15 Defendants that ForeCYTE Test was not fully cleared by the FDA for sale to the public in a site
 16 meeting in July 2012 and throughout the Class Period. Defendants, however, misrepresented this
 17 information to its investors. On October 4, 2013, Atossa acknowledged it did not possess the
 18 required FDA clearance to sell the ForeCYTE Test. Since that time, Atossa has generated zero
 19 revenue as a public company as it cannot sell its only product or generate revenue from testing
 20 from its only product: the ForeCYTE Test.

21
 22
 23
 24
 25
 26 ¹ In addition, Plaintiffs’ counsel has requested documents and information directly relevant to the allegations
 27 in this Complaint from the U.S. Food and Drug Administration (“FDA”) pursuant to the Freedom of Information Act,
 28 5 U.S.C. § 522, *et seq.*

INTRODUCTION

1 3. Atossa is a healthcare company that focuses on the development and marketing of
 2 cellular and molecular diagnostic risk assessment products for the detection of pre-cancerous
 3 conditions that could lead to breast cancer in the United States.

4 4. Atossa's only commercial product and sole revenue source is the ForeCYTE Test,
 5 which is a diagnostic test that purports to provide women with information regarding their
 6 individual risk of breast cancer. The ForeCYTE Test involves extracting and testing a specimen
 7 of nipple aspirate fluid ("NAF") from the breast milk duct, which is collected using Atossa's
 8 Mammary Aspirate Specimen Cytology Test ("MASCT") System - a patented breast pump (the
 9 "MASCT Device") and patient collection kit. Throughout Atossa's history, its operations have
 10 focused on the development of the MASCT System and the ForeCYTE Test, of which it is a part.

11 5. Indeed, prior to and during the Class Period, the success of the ForeCYTE Test was
 12 critical to Atossa's future. In 2010 and 2011 - prior to the marketing of the ForeCYTE Test - the
 13 Company generated total revenues of only \$1,500. Indicative of its precarious financial
 14 predicament, after a failed attempt at a public offering in 2011, Atossa had merely \$87,997 in cash
 15 and cash equivalents on hand to fund its operations in mid-2012 (just prior to the Class Period).

16 6. By the end of 2012, however, - after the initial, commercial rollout of the
 17 ForeCYTE Test - Atossa had generated \$481,842 in total revenues, 98% (\$475,402) of which came
 18 from the ForeCYTE Test, with the remaining 2% (\$6,440) coming from sales of the related
 19 MASCT System.

20 7. Despite the revenue from the rollout of the ForeCYTE Test, Atossa remained in
 21 dire need of funding to stay afloat. The Company made another attempt at a public offering in
 22

November 2012 - this time touting the purported efficacy and huge commercial potential of its new ForeCYTE Test, which it claimed was FDA-cleared.

8. Throughout the Class Period, Atossa issued a series of false and misleading statements regarding the ForeCYTE Test, claiming that it and the MASCT System incorporated therein were “FDA-cleared” for breast cancer screening and equating the ForeCYTE Test with mammograms and Pap smears which are widely used for cancer screening. Defendants claimed that if the ForeCyte Test could gain market acceptance equal to that of mammograms or Pap smears, Atossa could reach a market of between 39.3 million and 55 million women per year in the United States alone. For example, as stated by Defendant Steven C. Quay, the Company’s Chairman, President and Chief Executive Officer:

The ForeCYTE Test . . . is literally a Pap smear for breast cancer. As you may know, the Pap smear is a test for cervical cancer and takes a small scraping from the cervix and looks at the changes under the microscope and can see pre-cancer changes up to 10-years before cervical cancer appears. That test is the most successful screening test in all of medicine

We've never had the opportunity for that kind of test with the breast until now, and we're really excited to be able to offer a similar test for breast health . . . [The ForeCYTE Test] has gone through all the FDA clearance process, which is a multi-year, multi-million dollar process.²

9. However, the diagnostic feature of the ForeCYTE Test and the MASCT System (which is a component of the ForeCYTE Test), had never been cleared by the FDA for any purpose, much less breast cancer screening and diagnosis. FDA clearance is mandatory before any

² April Cashin-Garburt, "Breast Cancer Tests: an Interview with Dr. Steven Quay, CEO of Atossa Genetics," *NewsMedical* (February 22, 2013); found at <https://www.news-medical.net/news/20130222/Breast-cancer-tests-an-interview-with-Dr-Steven-Quay-CEO-of-Atossa-Genetics.aspx>.

1 device such as this can be marketed to doctors or patients. Indeed, there was no valid scientific
 2 data to show that ForeCYTE Test was an effective screening tool for any medical condition,
 3 including the detection of breast cancer or other breast disease.

4 10. Furthermore, Defendants knew prior to the Class Period that the ForeCYTE Test
 5 and MASCT System faced a significant risk of recall because these devices had not been FDA-
 6 cleared and were being illegally marketed. A July 2012 inspection report issued by the FDA
 7 following an inspection of Atossa's manufacturing facility warned the Company that neither
 8 product had been approved or cleared by the FDA as "safe and effective" and that the Company
 9 was in violation of numerous regulations for, among other things, its "misbranding" and illegal
 10 marketing of these "adulterated" products.

11 11. Although the Company learned of the significant likelihood of an FDA recall as
 12 early as July 2012, the market only began to get an inkling of the truth on February 25, 2013, when
 13 Atossa disclosed that on February 21, 2013, it had received a warning letter from the FDA
 14 regarding its MASCT System and the ForeCYTE Test. The Company, however, downplayed the
 15 significance of the warning letter, asserting that the primary concern of the FDA was simply a
 16 technical issue arising from a minor change to the MASCT System, which could be easily
 17 remedied. The Company misled the market by misrepresenting the seriousness of the FDA's
 18 findings regarding the Company's material alterations to the MASCT System which made it non-
 19 compliant with FDA regulations, and the Company's blatant violations of mandatory good
 20 manufacturing practices. In addition, the Company misled the public regarding serious findings
 21 of illegal marketing of the ForeCYTE Test by dismissively describing these findings as raising
 22 "certain issues with respect to the Company's marketing of the System."
 23

1 12. On this news, Atossa shares declined \$0.3869 per share or nearly 5.6%, to close at
 2 \$6.54 per share on February 25, 2013.

3 13. Over the next several months, the Company continued to publicly claim that the
 4 ForeCYTE Test was FDA-compliant, and proclaimed the great commercial potential of the
 5 ForeCYTE Test, and heralded smooth sailing through announcements of marketing and
 6 distribution agreements to sell the ForeCYTE Test and its components. Based on these
 7 representations, Atossa's stock price soared to \$12.37.

9 14. Meanwhile, unbeknownst to investors and despite its repeated assurances that its
 10 products were in full compliance with FDA standard, the Company submitted an application for
 11 FDA clearance of the ForeCYTE Test, which it later withdrew from consideration after receiving
 12 a response from the FDA which indicated that the FDA would not likely provide clearance. The
 13 Company disclosed none of these facts to the market.

15 15. Investors were thus shocked when the Company announced, after the markets
 16 closed on October 4, 2013, that the FDA had not only rejected the Company's response to the
 17 February 2013 Warning Letter as sufficiently deficient, but had compelled a recall of all the
 18 ForeCYTE Test products sold to date. At that time, the Company admitted for the first time:
 19

20 The MASCT device has not been cleared by the FDA for the
 21 screening or diagnosis of breast cancer. In addition, *the ForeCYTE*
 22 *[Test] has not been cleared or approved by the FDA for any*
 23 *indication*. The ForeCYTE [Test] and the MASCT device are not a
 24 replacement for screening mammograms, diagnostic imaging tests,
 25 or biopsies.

26 16. The FDA classified this recall as Class I, which means that the product is
 27 "dangerous or defective and has a reasonable chance of causing serious health problems or death."

17. On this news, Atossa shares declined \$2.47 per share, or more than 46%, to close at \$2.85 per share on October 7, 2013.

18. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

19. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-5].

20. This Court has jurisdiction over the subject matter of this action pursuant to 28
U.S.C. §1331, and § 27 of the Exchange Act.

21. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because Defendants maintain their principal office in this District, and many of the acts and omissions complained of herein occurred in substantial part in this District.

22. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of a national securities exchange.

PARTIES

23. Lead Plaintiffs, as set forth in their previously-filed Certifications (Dkt. #8-2), purchased Atossa shares at artificially inflated prices during the Class Period and have been damaged upon the issuance of the alleged corrective disclosures.

24. Plaintiff Paul Asher, as set forth in his attached Certification, purchased Atossa shares at artificially inflated prices during the Class Period and has been damaged upon the issuance of the alleged corrective disclosures.

25. Defendant Atossa is a Delaware corporation with principal executive offices located at 4105 East Madison Street, Suite 320, Seattle, Washington 98112. Atossa's common stock trades on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "ATOS."

26. Defendant Steven C. Quay (“Quay”) was at all relevant times, the Chairman, President, and Chief Executive Officer of Atossa. Quay oversaw the clinical testing and regulatory filing of the MASCT device with the FDA. Quay signed the false and misleading Registration Statements.

27. Quay is named as Defendant for violations of all Counts asserted herein, including violations of §§10(b), 20(a) and Rule 10b-5 of the Exchange Act.

SUBSTANTIVE ALLEGATIONS

A. Background

1. The FDA's Regulatory Regime for the Clearance and Marketing of Medical Devices

28. The Food, Drug and Cosmetic Act (the “FDCA”) and the U.S. Food and Drug Administration (“FDA”) play a major role in ensuring that only medical devices cleared by the FDA as safe and effective are marketed to patients. Products classified as Class I and Class II devices are eligible for marketing through what is known as “premarket notification” or 510(k). Section 510(k) of the FDCA requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance. Medical device manufacturers are required to submit a 510(k) premarket notification if they intend to introduce a device into commercial

1 distribution for the first time or reintroduce a device that has been significantly changed or
 2 modified to the extent that its safety or effectiveness could be affected.

3 29. To obtain 510(k) clearance for a medical device, an applicant must submit a 510(k)
 4 premarket notification to the FDA demonstrating that the device is “substantially equivalent” to a
 5 predicate device legally marketed in the United States. A showing of substantial equivalence
 6 sometimes, but not always, requires clinical data. A company cannot market or distribute its device
 7 until it is “FDA-cleared” - that is, the company receives a letter from the FDA authorizing the
 8 company to do so. A company may market a device only for the purposes specifically identified
 9 by the FDA in its “clearance” of the device.

10 2. **The Founding of Atossa Genetics, Inc. and the Development of the ForeCYTE Test
 11 and MASCT System**

12 30. Defendant Quay is no stranger to controversy in the biotech industry. Prior to
 13 founding Atossa, he was CEO of Washington-based Sonus Pharmaceuticals, Inc. (“Sonus”) in the
 14 1990s, and the Washington-based Nastech Pharmaceutical Co. (now MDRNA) for most of the last
 15 decade. Sonus flamed out under Quay’s successor a couple years ago, and was later absorbed by
 16 OncoGenex Pharmaceuticals (NASDAQ: OGXI). MDRNA is still alive, but has limited cash
 17 reserves, and its stock is currently priced and under \$1.00 per share. Quay left MDRNA in the fall
 18 of 2008 with a severance package worth \$1.7 million.

19 31. Quay’s latest endeavor, Atossa, is a healthcare company focused on the prevention
 20 of breast cancer through the commercialization of diagnostic medical devices and tests related to
 21 breast cancer. The Company’s leading diagnostic test, the ForeCYTE Test, involves the collection
 22 and testing of a specimen of nipple aspirate fluid (“NAF”), which is collected from the breast milk
 23 ducts using the Company’s Mammary Aspirate Specimen Cytology Test (“MASCT”) System. The
 24
 25
 26

1 MASCT System consists of a reusable hand-held pump (the “MASCT Device”) and a patient
 2 collection kit. An illustration of the ForeCYTE Test and MASCT System is provided below:



12 32. The MASCT System is a Class II medical “device” as defined by the FDCA. As
 13 such, it is regulated by the FDA and requires FDA clearance pursuant to a 510(k) premarket
 14 notification before it may be marketed in the United States. Defendant Quay oversaw the clinical
 15 testing and regulatory filing of the MASCT device with the FDA.
 16

17 33. The ForeCYTE Test includes the processing of NAF samples (collected with the
 18 MASCT System) by Atossa’s laboratory, which constitutes a Class II in-vitro diagnostic testing
 19 service. In-vitro diagnostic products are those reagents, instruments, and systems intended for use
 20 in diagnosis of disease or other conditions, including a determination of the state of health, in order
 21 to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the
 22 collection, preparation, and examination of specimens taken from the human body. As a Class II
 23 in-vitro diagnostic test service, the ForeCYTE Test is regulated by the FDA and requires premarket
 24 notification 510(k) before commercialization in the United States.
 25

1 34. Atossa was formed for the purpose of developing and marketing the MASCT
 2 System. The Company's operations began in December 2008 with the acquisition of the MASCT
 3 System patent rights and assignments, which was completed in January 2009. The Company was
 4 incorporated in Delaware on April 30, 2009. Since its inception, its operations have consisted
 5 primarily of securing manufacturing and distribution for the MASCT System.

6 35. Prior to Atossa's acquisition of the MASCT System's patent rights, in 2003 the
 7 MASCT System received FDA clearance pursuant to 510(k). At that time, the MASCT System
 8 was cleared by the FDA for use only as a sample collection device, with the provision that the fluid
 9 collected using this device can be used to determine and/or differentiate between normal, pre-
 10 cancerous, and cancerous cells. The MASCT System was not cleared by the FDA for the screening
 11 or diagnosis of breast cancer.

12 36. After initial attempts to market the MASCT System, the Company recognized that
 13 there are a number of other companies within the medical device industry that have products used
 14 in NAF collection that are similar, if not superior, to the MASCT System. In 2010, the Company
 15 generated zero revenue. In 2011, it generated only \$1,500.

16 37. The Company's cash position had diminished to the point where the founders of
 17 the Company were unable to finance the Company at the level needed for growth. Seeking to raise
 18 capital through a public offering, the Company filed a registration statement on Form S-1 with the
 19 SEC in October 2010, which it was forced to withdraw in February 2011. The withdrawal of the
 20 registration statement further weakened the company's position.

21 38. In dire straits, the Company sought to capitalize on the MASCT System by adding
 22 a cancer screening feature, the ForeCYTE diagnostic test, and marketing all the features as a single
 23

1 medical system/device - the ForeCYTE Test. However, the Company never sought FDA clearance
 2 through submission of a 510(k) premarket notification for either the ForeCYTE diagnostic test or
 3 the combined system that was the ForeCYTE Test.

4 39. During this time, the Company also significantly altered the MASCT System. As
 5 originally cleared by the FDA, the NAF specimen was to be washed from the collection membrane
 6 with fixative solution into the collection vial. Following its alteration, the user was instructed to
 7 apply one spray of the fixative to the collection membrane, which fixes the NAF specimen to the
 8 filter paper rather than washing it into a collection vial.

9 40. This change to the MASCT System significantly impacted the safety and
 10 effectiveness of the device and required the Company to seek FDA clearance through submission
 11 of a new 510(k) premarket notification. The Company never made such a submission.

12 41. In December 2011, the Company began limited-marketing of the ForeCYTE Test
 13 to physicians, primarily obstetric-gynecologists, as well as breast health and mammography
 14 clinics, for use in conjunction with other health screening examinations, including annual physical
 15 examinations and regularly scheduled cervical Pap smears and mammograms. The Company
 16 marketed the ForeCYTE Test, as well as the MASCT System, as “FDA-cleared”.

17 42. As a result, in 2012, Atossa’s revenues jumped to \$481,842, 98% (\$475,402) of
 18 which came from the ForeCYTE diagnostic testing services, with the remaining 2% (\$6,440)
 19 coming from sales of the related MASCT System (the MASCT Device and patient collection kits).
 20 The ForeCYTE Test was the Company’s sole source of revenues. Indeed, as the Company itself
 21 recognized, the MASCT System would not have any market at all without the analytical services
 22 provided in the form of the ForeCYTE diagnostic test.

1 43. With the new, apparently lucrative ForeCYTE Test, the Company attempted
 2 another public offering. On or about February 14, 2012, Atossa filed with the SEC a Form S-1
 3 Registration Statement (the “S-1 Registration Statement”), beginning the process toward what
 4 would be the Company’s initial public offering in November 2012.

5 44. In July 2012, while the Company was in the process of finalizing the Registration
 6 Statement, the FDA inspected Atossa’s facilities. The inspection lasted from July 16, 2012 through
 7 July 25, 2012.

9 45. During the inspection, the FDA determined that the MASCT System was
 10 “adulterated” under Section 501(h) of the FDCA, and violated the Current Good Manufacturing
 11 Practices (“cGMP”) requirements of the Quality System regulation found under Title 21, Code of
 12 Federal Regulations (CFR), Part 820. The inspection revealed numerous additional violations,
 13 including but not limited to those of 21 CFR 803.17; 807.81(a)(3)(i); 820.20(c); 820.20(d); 820.22;
 14 820.30(a); 820.30(i); 820.50(a); 820.100(a); 820.184; and 820.198(e).

16 46. Specifically, the FDA discovered what the Company already knew - that after the
 17 MASCT System received 510(k) clearance in 2003, Atossa had made substantial modifications to
 18 the NAF specimen collection process. The FDA determined that this change could significantly
 19 affect its safety or effectiveness and required the submission of another 510(k) to the FDA
 20 demonstrating that the new process/device is safe and effective. Because Atossa had never
 21 submitted a request for approval of the changes, the MASCT System that Atossa had been
 22 marketing and selling was (1) not FDA-cleared, (2) “adulterated” under section 501(f)(1)(B) of
 23 the FDCA, [21 U.S.C § 351(f)(1)(B)], (3) “misbranded” under section 502(o) of the FDCA, [21
 24 U.S.C. § 352(o)], and (4) being marketed illegally by the Company.

1 47. The FDA also determined that the ForeCYTE Test required independent approval
 2 or clearance before marketing, which had never been sought.³ Thus, the ForeCYTE Test was
 3 misbranded under Section 502(a) of the FDCA [21 U.S.C. 352(a)] (and 21 CFR 807.97). In
 4 particular, the FDA charged that Atossa's marketing literature that represented the MASCT
 5 System and the ForeCYTE Test as "FDA-approved" and/or "FDA-cleared" for breast cancer
 6 screening and diagnosis was misleading and illegal.
 7

8 48. Of course, Defendants were well aware that neither the MASCT System nor the
 9 ForeCYTE Test had been cleared by the FDA because Atossa had never submitted the required
 10 510(k) notification for either.

11 49. The Defendants also knew that without the ForeCYTE Test - Atossa's only current
 12 and potential source of revenue - the upcoming public offering would fail to raise the funding that
 13 Atossa needed to continue.

14 **B. False and Misleading Statements Regarding the Forecyte Test and Mascet System**

15 **1. The Q3 2012 Quarterly Statement and Press Release**

16 50. On December 20, 2012, the Company issued a press release announcing its
 17 financial results for the third quarter ended September 30, 2012. For the quarter, the Company
 18 reported a net loss of \$1,143,382, or \$0.10 diluted loss per share ("LPS") and revenue of \$105,576,
 19 as compared to net loss of \$1,272,680, or \$0.11 diluted LPS, for the same period the year prior.
 20 Discussing the success of the initial public offering, Defendant Quay stated that "[t]he proceeds
 21 from the IPO will enable us to accelerate the national roll-out of our first ***FDA-cleared and***
 22

23
 24
 25
 26 ³ See <http://wayback.archive-it.org/7993/20170111092842/http://www.fda.gov/MedicalDevices/Safety/ListOfRecalls/ucm374600.htm> (previously available at <http://www.fda.gov/MedicalDevices/Safety/ListOfRecalls/ucm374600.htm>).

1 *marketed product, the ForeCYTE [Test] for breast cancer risk assessment.”* (emphasis added).

2 The press release also described the ForeCYTE Test as “patented, **FDA-cleared diagnostic**
 3 **medical devices and patented, laboratory developed tests (LDT) that can detect precursors to**
 4 **breast cancer up to eight years before mammography”** that is “akin to the Pap Smear.”

5 51. The foregoing representations in ¶ 50 were materially false and misleading because
 6 they misrepresented and failed to disclose the following adverse facts, which were known to
 7 Defendants or recklessly disregarded by them, including that:

- 9 a. The ForeCYTE Test had never been clinically tested as a cancer screening device;
- 10 b. The ForeCYTE Test never was approved or cleared by the FDA;
- 11 c. The FDA inspection in July 2012 had found that the Company’s marketing of the
 12 ForeCYTE Test and the MASCT System violated FDA regulations due to the
 13 foregoing; and
- 14 d. The FDA inspection in July 2012 had found that the Company’s facilities were in
 15 violation of, among other things, FDA mandated Good Manufacturing Practices
 16 (cGMP) regulations.

18 2. **The February 2013 Interview With Defendant Quay**

19 52. On February 2013, Defendant Quay was interviewed regarding the ForeCYTE Test
 20 and continued to insist that it was FDA approved. In addition, Quay continue to push the meme
 21 that the ForeCYTE Test was the equivalent of a Pap smear for breast cancer - and with the potential
 22 for similar wide-scale usage:

23 The ForeCYTE Test . . . is literally a Pap smear for breast cancer.
 24 As you may know, the Pap smear is a test for cervical cancer and
 25 takes a small scraping from the cervix and looks at the changes
 26 under the microscope and can see pre-cancer changes up to 10-years

1 before cervical cancer appears. That test is the most successful
 2 screening test in all of medicine....

3 * * *

4 We've never had the opportunity for that kind of test with the breast
 5 until now, and we're really excited to be able to offer a similar test
 6 for breast health . . . [The ForeCYTE Test] has gone through all of
 7 the FDA clearance process, which is a multi-year, multi-million
 8 dollar process.⁴

9 53. The foregoing representations in ¶ 52 were materially false and/or misleading for
 10 the reasons set forth in ¶ 51.

11 **3. The Warning Letter Assurances**

12 54. On February 25, 2013, the Company issued a press release announcing that it had
 13 received a Warning Letter from the FDA dated February 20, 2013 (the "Warning Letter")
 14 regarding its MASCT System and the ForeCYTE Test of which it is a part. The press release
 15 described the Warning Letter as "aris[ing] from certain FDA findings during a July 2012
 16 inspection," and characterized the thrust of the FDA's concerns as a technical violation relating to
 17 the modification to the MASCT System:

18 FDA alleges in the Letter that following 510(k) clearance the
 19 Company changed the System in a manner that requires submission
 20 of an additional 510(k) notification to the FDA. Specifically, the
 21 FDA observes that the Instructions For Use (IFU) in the original
 22 510(k) submission stated that the user must "Wash the collection
 23 membrane with fixative solution into the collection vial..." and the
 24 current IFU states "...apply one spray of Saccomanno's Fixative to
 25 the collection membrane..." and that "this change fixes the NAF
 26 specimen to the filter paper rather than washing it into a collection
 27 vial.

28 ⁴ April Cashin-Garbutt, "Breast Cancer Tests: an Interview with Dr. Steven Quay, CEO of Atossa Genetics," *NewsMedical* (February 22, 2013); found at <https://www.news-medical.net/news/20130222/Breast-cancer-tests-an-interview-with-Dr-Steven-Quay-CEO-of-Atossa-Genetics.aspx>.

1 55. The issues concerning the Company's misleading marketing of the ForeCYTE Test
 2 and MASCT System as FDA-cleared for cancer screening was relegated to a single dismissive
 3 statement: "The Letter also raises certain issues with respect to the Company's marketing of the
 4 System and the Company's compliance with FDA Good Manufacturing Practices (cGMP)
 5 regulations, among other matters."

6 56. The Company downplayed the significance of the Warning Letter by assuring
 7 investors of the Company's full compliance with FDA regulations: "[Our] response will explain
 8 why the Company believes that the System in its current form has been and continues to be
 9 appropriately marketed under a cleared 510(k) premarket notification, and why it is in substantial
 10 compliance with applicable regulations, including cGMP." The Company also told investors that
 11 even if the FDA was unpersuaded by the Company's response, remedying the violation would
 12 simply require submitting new paperwork or reverting to the prior version of the MASCT System:
 13 "If the FDA does not agree with the Company's position concerning clearance of the System,
 14 Atossa may be required to submit and receive clearance of a new 510(k) notice for the current
 15 form of the System or revert to marketing the System using the prior NAF processing method."

16 57. Despite disclosure of the FDA warning letter, Atossa's shares declined \$0.3869 per
 17 share or only 5.6%, to close at \$6.54 per share on February 25, 2013. The market believed and
 18 relied on Atossa's representations that the FDA warning letter would be readily resolved.

19 58. The foregoing representations in ¶¶ 54-57 were materially false and/or misleading
 20 for the reasons set forth in ¶ 51. In addition, the foregoing representations omitted to disclose that
 21 the FDA raised concerns to Defendants that the FDA had not cleared or approved the ForeCYTE
 22 test for any application.

1 59. The same day as the Company's announcement of the Warning Letter, Dawson
 2 James Securities, Inc., an underwriter of the Company's initial public offering that also assisted in
 3 the preparation and dissemination of Atossa's offering documents, released an analyst report
 4 repeating the Company's misleading characterization of the FDA's position as being focused
 5 primarily on the technical changes to the MASCT System, adding that "[t]he new processing
 6 method simply provided an easier method for nurses and other healthcare providers to prepare the
 7 sample for laboratory testing, and the product benefits of the MASCT System are still evident
 8 under the original sample preparation method." Dawson concluded by asserting the following:
 9

10 We believe that Atossa will be able to suitably reply to the FDA's
 11 concerns as expressed in the Warning Letter and that even if a new
 12 501(k) application is required for the new sample preparation
 13 method, Atossa will be able to continue marketing its MASCT
 14 system under the original method, thus we are maintaining our Buy
 15 rating on ATOS shares and \$10.00 price target.

16 60. Following the FDA Warning Letter, the Company went on the offensive to assure
 17 investors that Atossa's business, which hinged on the ForeCYTE Test, would not be significantly
 18 impacted by the FDA's concerns. It did this by entering into marketing and distribution
 19 agreements, which the Company knew investors would take as a sign that the MASCT System and
 20 ForeCYTE Test were not in jeopardy of FDA suspension or recall.

21 **4. The FedMed Announcement**

22 61. For example, on March 13, 2013 Atossa announced that it entered into an
 23 agreement with FedMed, Inc., one of the largest proprietary Preferred Provider Organization
 24 networks in the U.S., for diagnostic laboratory testing. Upon the announcement, Defendant Quay
 25 stated: "There is a significant unmet clinical need in the medical community for more effective
 26

1 ways to identify women at high risk of breast cancer," and "Our agreement with FedMed will help
 2 ensure that more doctors and their patients have access to the ForeCYTE [Test]. . ."

3 62. On March 13, 2013, Atossa stock rose 17.3% to a high of \$7.74 during the day,
 4 closing at \$6.93, and was among NASDAQ stocks posting the largest percentage increases on that
 5 day. Also, approximately 451,700 shares changed hands, a 3,690.7 percent increase over its 65-
 6 day average volume.
 7

8 **5. The March 15, 2013 Interview with Defendant Quay**

9 63. On Friday March 15, 2013, Defendant Quay gave an interview, which was also
 10 published on Monday March 18, 2013. Noting that the Company's stock "is up about 25% since
 11 the IPO", Quay emphasized the FDA clearance of its devices and downplayed the risk to the
 12 national rollout of the ForeCYTE Test: "I mean, 2013 and 2014 are execution years, where **FDA**
 13 **clearance risk has been achieved**, patents have been obtained, clinical trials have been achieved,
 14 manufacturing has been achieved—**so now it's really a matter of going from less than 100 doctors**
 15 **doing our test to the expectation of thousands of doctors.**" (Emphasis added.)

17 64. On Friday March 15, 2013 Atossa stock rose 11.1% (\$.74) to \$7.40. It was among
 18 NASDAQ stocks posting the largest percentage increases in price and volume on that day.
 19 Approximately 513,500 shares changed hands, a 2,457.1 percent increase over its 65-day average
 20 volume. On Monday March 18, 2013, Atossa stock rose another 24.5% (\$1.81) to \$9.21, and was
 21 among NASDAQ stocks posting the largest percentage increases in price and volume on that day.
 22 Approximately 475,400 shares changed hands, a 1,595.3 percent increase over its 65-day average
 23 volume. On March 19, 2013, Atossa stock rose another 34.3% (\$3.16) to \$12.37, as it was the
 24 largest percentage price gainer on the NASDAQ and among those posting the largest volume
 25
 26

1 increase. Approximately 921,500 shares changed hands, a 2,482.0 percent increase over its 65-day
 2 average volume.

3 65. The foregoing representations in ¶ 63 were materially false and misleading for the
 4 reasons set forth in ¶ 51. In addition, the foregoing representations omitted to disclose that the
 5 FDA raised concerns to Defendants that the FDA had not cleared or approved the ForeCYTE test
 6 for any application.

7 **6. The 2012 Annual Report**

8 66. On March 28, 2013, the Company filed an annual report for the year ended
 9 December 31, 2012 on a Form 10-K with the SEC, which was signed by Defendant Quay. For the
 10 year, the Company reported net loss of \$5,079,851, or \$0.41 diluted LPS and revenue of \$481,842,
 11 as compared to net loss of \$3,442,269, or \$0.38 diluted LPS and revenue of \$1,500 for the prior
 12 year. In addition, the Form 10-K contained signed certifications pursuant to SOX by Defendant
 13 Quay, stating that the financial information contained in the Form 10-K was accurate and disclosed
 14 any material changes to the Company's internal control over financial reporting. In the
 15 accompanying press release, Defendant Quay stated: "We continue to make steady progress in the
 16 national rollout of our patented ForeCYTE [Test], advancing our ambition to arm women and their
 17 physicians with information that will enable improved breast health management and prevent
 18 breast cancer."

22 67. Regarding the FDA Warning Letter, the Form 10-Q stated: "We are reasonably
 23 confident in our responses to the FDA. Consequently, no provision or liability has been recorded
 24 as of December 31, 2012 as a result of the Letter."

1 68. The market bought into the assurances and posturing of the Company in the wake
 2 of the FDA Warning Letter. For example, a March 28, 2013 analyst report by Zack's Investment
 3 Research rated Atossa shares "Outperform" stating that "National rollout of ForeCYTE is on
 4 track" and that "[b]ased on the agreement with FedMed, we have raised our revenue forecast for
 5 2013 and beyond." Addressing the FDA Warning Letter, the analyst report relied on
 6 representations received directly from the Company to conclude "We think the FDA letter won't
 7 impact Atossa's major business much", explaining, "***based on our conversation with the
 8 Company, we have reasons to believe that the new version of MASCT System is in compliance
 9 with the FDA regulations and not required for 510(K) clearance.***" (emphasis added).
 10

11 69. Emboldened by the market's acceptance of its assertions that FDA clearance was
 12 not at risk, the Company ramped up its marketing of the ForeCYTE Test.
 13

14 7. **The April 2013 Press Releases**

15 70. On April 15, 2013, in a press release purporting to announce the launch of a new
 16 "Nationwide Awareness Program" for its "Breast Cancer Prevention Test", the Company
 17 proclaimed that the ForeCYTE Test was equivalent, and even superior, to the Pap smear and
 18 mammogram. The press release stated: (1) the ForeCYTE Test is the "Pap smear for the breast"
 19 for early detection of cancerous cells"; (2) "[w]hile mammograms can detect cancer, Atossa's test
 20 detects treatable pre-cancerous conditions in the breast up to eight years before cancer arises"; and
 21 (3) "women with dense breasts, whom research shows may be at a higher risk for breast cancer
 22 and for whom mammograms are often less reliable, can be tested easily with the ForeCYTE test
 23 in their healthcare providers' office". Inexcusably capitalizing on women's fear of breast cancer,
 24 the Company represented that "***[the ForeCYTE Test] can provide vital early detection of cancer***
 25

1 or pre-cancerous conditions that may progress to cancer over an approximately eight-year period
 2 and ***before cancer can be detected by mammography*** or other means and without the risks of
 3 radiation, especially in women younger than age 50. No invasive biopsy needles or open surgical
 4 incisions are used in the Atossa test and the test is painless.” (Emphasis added.)

5 71. An April 23, 2013, press release similarly states that “the analysis in a woman with
 6 no family history may detect pre-cancerous changes -- up to eight years before a tumor is large
 7 enough to be spotted on a mammogram. ***That pinpoints a woman’s exact risk of developing***
 8 ***cancer*** and allows any pre-cancer to be treated with drugs. . .” (emphasis added)

9 72. An April 29, 2013, press release states, “Unlike mammograms, which are
 10 commonly recommended for women starting at age 40 to 50, the ForeCYTE [Test] is more age
 11 agnostic, uses no radiation and does not require invasive biopsy needles or surgical incisions.”

12 8. **The Millennium HealthCare Announcement**

13 73. On May 2, 2013, following on it prior announcement of an agreement with FedMed
 14 to expand access to the ForeCYTE Test, Atossa announced that it signed an agreement with
 15 Millennium HealthCare Inc. for the distribution of Atossa’s MASCT System and that Millennium
 16 had submitted an initial order for 10,000 MASCT patient kits.

17 9. **The Q1 2013 Quarterly Report and Press Release**

18 74. On May 15, 2013, the Company announced the filing of a quarterly report for the
 19 first quarter ended March 31, 2013. In the press release, Defendant Quay stated: “The national
 20 rollout of our ForeCYTE [Test] is proceeding well and we are pleased with the response we are
 21 getting from the physician community and from patients.” Defendant Quay continued: “We
 22 anticipate signing up additional distributors this year and continuing to build our internal sales and
 23 marketing team.”

1 75. On the same day, the Company filed a quarterly report for the first quarter ended
 2 March 31, 2013 on a Form 10-Q with the SEC, which contained many of the statements identified
 3 above from the Company's prior filings, and which was signed by Defendant Quay. For the
 4 quarter, the Company reported a net loss of \$1,941,440, or \$0.14 diluted LPS and revenue of
 5 \$182,670, as compared to a net loss of \$1,062,918, or \$0.09 diluted LPS and revenue of \$54,713
 6 for the same period a year ago. In addition, the Form 10-Q contained signed certifications pursuant
 7 to SOX by Defendant Quay, stating that the financial information contained in the Form 10-Q was
 8 accurate and disclosed any material changes to the Company's internal control over financial
 9 reporting. Regarding the FDA Warning Letter, the Company continued to represent that "The
 10 Company is reasonably confident in its responses to the FDA. Consequently, no provision or
 11 liability has been recorded as of March 31, 2013 as a result of the Letter."

14 76. The market continued to rely on the Company's "confident" representations of
 15 smooth sailing. A May 22, 2013 analyst report titled "BUY Marketing blitz continues for Atossa"
 16 recounted the various marketing and distribution agreements entered into by the Company as well
 17 as the announcement that two leading breast centers in Texas would soon begin to offer the
 18 ForeCYTE test: "***with two approved products and an active and innovative marketing program***
 19 in a very high-profile and large area of medical need, an improved balance sheet and recently
 20 added access to capital . . . ***there are many reasons for investors to hang onto their ATOS***
 21 ***shares . . .***" (Emphasis added.)

23 **10. The HealthSmart and Fisher HealthCare Announcements**

24 77. On June 17, 2013, the Company announced that it had entered into a contractual
 25 agreement with HealthSmart, a PPO network serving clients in all 50 states. Defendant Quay
 26

1 stated: "The agreement with HealthSmart, our third agreement with a PPO organization, will help
 2 more doctors and patients access the ForeCYTE test."

3 78. On June 20, 2013, the Company announced that it had signed another distribution
 4 agreement, this time with Fisher HealthCare Inc., for distribution of the ForeCYTE Test's MASCT
 5 patient collection kit and the MASCT Device.

6 79. At the same time as the Company was assuring the market in its May second quarter
 7 Form 10-Q that the Company was "confident" in its response to the FDA that the ForeCYTE Test
 8 and MASCT System were appropriately marketed under a cleared 510(k) premarket notification,
 9 the Company was actually preparing and filing a new 510(k) premarket notification with the FDA.

10 80. In August 2013, the Company was forced to withdraw the new 510(k) premarket
 11 notification on the 89th day of the 90-day FDA review window. The withdrawal came after the
 12 Company received a response from the FDA which indicated that the FDA would likely not clear
 13 the 510(k) submission during the applicable time frame. None of these facts were disclosed to
 14 investors.

15 **11. The Quarterly Report for Q2 2013 and Press Release**

16 81. On August 14, 2013, the Company filed a quarterly report for the second quarter
 17 ended June 30, 2013 on a Form 10-Q with the SEC, which contained many of the statements
 18 identified above from the Company's prior filings, and was signed by Defendant Quay. For the
 19 quarter, the Company reported a net loss of \$2,583,699, or \$0.17 diluted LPS and revenue of
 20 \$326,078, as compared to a net loss of \$1,167,948, or \$0.10 diluted LPS and revenue of \$223,097
 21 for the same period a year ago. In addition, the Form 10-Q contained signed certifications pursuant
 22 to SOX by Defendant Quay, stating that the financial information contained in the Form 10-Q was
 23

1 accurate and disclosed any material changes to the Company's internal control over financial
 2 reporting. Regarding the FDA Warning Letter, the Form 10-Q continued to represent that "The
 3 Company is reasonably confident in its responses to the FDA. Consequently, no provision or
 4 liability has been recorded as of June 30, 2013 as a result of the Letter."

5 82. In the August 14 press release Defendant Quay stated: "Interest in our ForeCYTE
 6 test continues to grow, as evidenced by the increasing numbers of doctors signing up to provide
 7 the test and the increasing number of doctors submitting specimens to our lab for analysis. . . . We
 8 will continue to sign up new doctors while focusing intently on driving volume from existing
 9 doctors through a comprehensive follow up program. In addition, we are working closely with our
 10 marketing partners to create awareness, interest and further adoption of the ForeCYTE test among
 11 general practitioners, OB/GYNs, breast clinics and hospitals."

12 83. Based on these financial results - and left in the dark as to the true status of the
 13 MASCT System and ForeCYTE Test- analysts continued to rate Atossa stock "Outperform". For
 14 example, an August 15, 2013 analyst report with the headline "Record revenue reported in 2Q13
 15 following national rollout of ForeCYTE" stated that "Sales will continue to grow due to focused
 16 market strategy":

17 We are pleased to see that Atossa reported record revenue for the
 18 second quarter 2013. We believe as the Company continues to roll
 19 out its ForeCYTE tests nationally, revenue growth will accelerate in
 20 the coming quarters and years ***thanks to its focused marketing***
 21 ***strategy*** and continued new products/services offering. . . . ***All these***
 22 ***promotion efforts have created concrete effects for the Company.***
 23 Starting with 37 medical professionals offering the ForeCYTE test
 24 at the beginning of the year, there were 154 doctors offering the test
 25 at the end of the second quarter and 243 as of July 31, 2013. The
 26 number of tests received by Atossa's laboratory increased 50%
 sequentially in the second quarter 2013 compared to the first quarter.

All these indicate that sales will continue to grow in the future.
(Emphasis added.)

12. The McKesson Announcement

84. On September 18, Atossa announced a nationwide distribution agreement with McKesson Medical-Surgical to sell and distribute the ForeCYTE Test's MASCT Device and patient collection kits, effectively completing the Company's nationwide rollout of the ForeCYTE Test. Defendant Quay lauded the agreement as "another important step forward in making the ForeCYTE test the standard of care in breast cancer risk assessment", and that "we look forward to providing physicians a much needed early warning system by detecting the earliest, reversible precursors of breast cancer."

85. On September 19, the shares of Atossa soared 21.0% (\$1.04) on more than 37-times the normal daily trading volume, closing at \$6.00. At its highest level, the stock had advanced 56.3%, touching \$7.75 a share. Approximately 8,196,400 shares changed hands, a 10,262.2 percent increase over its 65-day average volume. Atossa shares were the second highest volume gainer on the NASDAQ that day.

86. On September 19, 2013 the FDA contacted the Company, informing it that it must recall the MASCT System and ForeCYTE Test because of the Company's continued marketing without FDA approval or clearance. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.⁵

⁵ See <http://wayback.archive-it.org/7993/20170111092842/http://www.fda.gov/MedicalDevices/Safety/ListOfRecalls/ucm374600.htm> (previously available at <http://www.fda.gov/MedicalDevices/Safety/ListOfRecalls/ucm374600.htm>).

1 87. Continuing to encourage investors to believe that the Company's only products
 2 were viable, on September 25, 2013, Defendant Quay conducted a webinar via The Money Show,
 3 titled "How to Invest Ahead of Breast Cancer Awareness Month." Quay made no mention on this
 4 webinar of the FDA recall demand.

5 88. An October 3, 2013 Form 4 filing with the SEC reveals that Defendant Quay sold
 6 7,265 shares of Atossa stock on October 1, at a weighted average of \$5.658 per share.
 7

8 **C. The Truth Emerges Regarding Defendants' Fraud**

9 89. Three days after these October 1, 2013 insider sales, the Company disclosed that,
 10 consistent with the FDA demand, it was recalling the ForeCYTE Test and MASCT System from
 11 the market as a result of "concerns raised by the U.S. Food and Drug Administration (FDA) in a
 12 warning letter received by Atossa in February 2013." It was upon this announcement that the
 13 market learned for the first time that:

14 The MASCT device has not been cleared by the FDA for the
 15 screening or diagnosis of breast cancer. In addition, the ForeCYTE
 16 [Test] has not been cleared or approved by the FDA for any
 17 indication. The ForeCYTE [Test] and the MASCT device are not a
 18 replacement for screening mammograms, diagnostic imaging tests,
 19 or biopsies.

20 90. The market was shocked by this announcement. Investors finally realized that the
 21 Company's blitz marketing and national rollout of the ForeCYTE Test was a complete sham,
 22 perpetrated to dupe consumers and investors as to the safety, effectiveness and legality of Atossa's
 23 only product. Some analysts immediately suspended coverage of the Company, stating that prior
 24 estimates for the Company should not be relied upon. As a result, Atossa shares declined \$2.47
 25 per share, or more than 46%, to close at \$2.85 per share on October 7, 2013, as shown on the chart
 26 below:



91. It was only after the recall and the loss to investors that the market learned (i) that
 10 the FDA had previously warned the Company that the ForeCYTE Test did not have required FDA
 11 approval/clearance, (ii) that the Company had attempted and failed to gain FDA clearance in the
 12 summer of 2013, and (iii) that the recall of the MASCT System would cause the Company's
 13 distributors not to sell the MASCT System and ForeCYTE Test.

15 ADDITIONAL ALLEGATIONS

16 92. Subsequent to the recall of the ForeCYTE Test and MASCT System, there has been
 17 a changing of the guard at Atossa. On December 18, 2013, Alexander Cross announced his
 18 retirement from the Atossa Board so that he "could pursue other personal and professional
 19 activities." Similarly, on January 31, 2014, John Barnhart announced his retirement from Atossa's
 20 Board, also for the purported purpose of "pursue[ing] other personal and professional activities."

22 93. On April 2, 2014, Atossa announced that Ben R. Chen joined the Company as
 23 Senior Vice President of Global Regulatory Affairs and Quality Assurance, a newly created
 24 position. Mr. Chen will now oversee all facets of Atossa's regulatory affairs, providing oversight

1 for all U.S. and international regulatory matters, including filings and interactions with regulatory
 2 authorities, and all quality assurance matters.

3 94. In addition, Atossa altered its website in early 2014 such that its product page,
 4 which previously made representations regarding the virtues of the ForeCYTE Test and the FDA-
 5 cleared MASCT System, is now “under construction” and contains no reference to these products.

6 95. In perhaps a further effort to erase the past, Plaintiffs’ private investigator, who has
 7 been attempting to contact former employees of Atossa, has advised that these former employees
 8 appear to have been contacted by Company officials and advised not to provide any information
 9 concerning Atossa.

10 96. Finally, in its 2013 Form 10-K, filed with the SEC, Atossa has admitted that “The
 11 MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer.
 12 In addition, our NAF cytology test has not been cleared or approved by the FDA for any indication
 13 . . .” Form 10-K at 6. Atossa further admitted that “as a result of the recall of the MASCT System
 14 in October 2013, our product revenue and service revenue have ceased. We do not anticipate
 15 generating revenue until and unless we receive an additional 510(k) clearance from the FDA for
 16 our ForeCYTE Breast Aspirator and re-launch the device.” Id at 55.

17 **PLAINTIFFS’ CLASS ACTION ALLEGATIONS**

18 97. Plaintiffs brings this action as a class action pursuant to Federal Rule of Civil
 19 Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons or entities who acquired
 20 Atossa shares during the Class Period and/or pursuant or traceable to the Company’s false and
 21 misleading Registration Statement for its IPO, and who were damaged thereby (the “Class”).
 22 Excluded from the Class are Defendants, the officers and directors of Atossa, members of Quay’s
 23
 24
 25
 26

1 immediate family and their legal representatives, heirs, successors or assigns and any entity in
 2 which Quay has or had a controlling interest.

3 98. The members of the Class are so numerous that joinder of all members is
 4 impracticable. Throughout the Class Period, Atossa shares were actively traded on the NASDAQ.
 5 While the exact number of Class members is unknown to Plaintiffs at this time and can be
 6 ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds, if not
 7 thousands of members in the proposed Class.

9 99. Plaintiffs' claims are typical of the claims of the members of the Class as all
 10 members of the Class are similarly affected by Defendants' wrongful conduct in violation of
 11 federal law that is complained of herein.

12 100. Plaintiffs will fairly and adequately protect the interests of the members of the Class
 13 and have retained counsel competent and experienced in class and securities litigation. Plaintiffs
 14 have no interests antagonistic to or in conflict with those of the Class.

16 101. Common questions of law and fact exist as to all members of the Class and
 17 predominate over any questions solely affecting individual members of the Class. Among the
 18 questions of law and fact common to the Class are:

- 20 a. whether the Exchange Act was violated by Defendants' acts as alleged herein;
- 21 b. whether statements made by Defendants to the investing public during the Class
 22 Period misrepresented material facts about the financial condition, business, and
 23 prospects of Atossa;

- c. whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- d. whether Defendants caused Atossa to issue false and misleading financial statements during the Class Period;
- e. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- f. whether the prices of Atossa shares during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- g. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

102. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

103. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- a. Atossa shares met the requirements for listing, and were listed and actively traded on the NASDAQ Global Select Market, a highly efficient and automated market;
- b. As a public issuer, Atossa filed periodic public reports with the SEC and the NASDAQ:

- c. Atossa regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- d. Atossa was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

104. Based on the foregoing, the market for Atossa shares promptly digested current information regarding Atossa from all publicly available sources and reflected such information in the prices of the shares, and Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

COUNT II

**FOR VIOLATIONS OF SECTION 10(B) AND RULE 10B-5 PROMULGATED
THEREUNDER**

(AGAINST ATOSSA AND QUAY)

105. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

106. This Count is asserted against Atossa and Quay and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

107. During the Class Period, Atossa and Quay, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to

1 disclose material facts necessary in order to make the statements made, in light of the
2 circumstances under which they were made, not misleading.

3 108. Atossa and Quay violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- 4 a. employed devices, schemes and artifices to defraud;
- 5 b. made untrue statements of material facts or omitted to state material facts necessary
6 in order to make the statements made, in light of the circumstances under which
7 they were made, not misleading; or
- 8 c. engaged in acts, practices and a course of business that operated as a fraud or deceit
9 upon plaintiffs and others similarly situated in connection with their purchases of
10 Atossa common stock during the Class Period.

12 109. Atossa and Quay acted with scienter in that they knew that the public documents
13 and statements issued or disseminated in the name of Atossa were materially false and misleading;
14 knew that such statements or documents would be issued or disseminated to the investing public;
15 and knowingly and substantially participated, or acquiesced in the issuance or dissemination of
16 such statements or documents as primary violations of the securities laws. These Defendants by
17 virtue of their receipt of information reflecting the true facts of Atossa, their control over, and/or
18 receipt and/or modification of Atossa's allegedly materially misleading statements, and/or their
19 associations with the Company which made them privy to confidential proprietary information
20 concerning Atossa, participated in the fraudulent scheme alleged herein.

22 110. Quay, who was a senior officer of the Company, had actual knowledge of the
23 material omissions and/or the falsity of the material statements set forth above, and intended to
24 deceive Plaintiffs and the other members of the Class, or, in the alternative, acted with reckless
25

1 disregard for the truth when they failed to ascertain and disclose the true facts in the statements
2 made by them or other Atossa personnel to members of the investing public, including Plaintiffs
3 and the Class.

4 111. As a result of the foregoing, the market price of Atossa common stock was
5 artificially inflated during the Class Period. In ignorance of the falsity of the statements by Atossa
6 and Quay, Plaintiffs and the other members of the Class relied on the statements described above
7 and/or the integrity of the market price of Atossa securities during the Class Period in purchasing
8 Atossa common stock at prices that were artificially inflated as a result of Atossa and Quay's false
9 and misleading statements.

10 112. Had Plaintiffs and the other members of the Class been aware that the market price
11 of Atossa common stock had been artificially and falsely inflated by Atossa and Quay's misleading
12 statements and by the material adverse information which Atossa and Quay did not disclose, they
13 would not have purchased Atossa common stock at the artificially inflated prices that they did, or
14 at all.

15 113. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of
16 the Class have suffered damages in an amount to be established at trial.

17 114. By reason of the foregoing, Atossa and Quay have violated Section 10(b) of the
18 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiffs and the other
19 members of the Class for substantial damages which they suffered in connection with their
20 purchase of Atossa common stock during the Class Period.

COUNT II

**VIOLATION OF SECTION 20(A) OF THE EXCHANGE ACT
(AGAINST QUAY)**

115. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

116. During the Class Period, Defendant Quay participated in the operation and management of Atossa, and conducted and participated, directly and indirectly, in the conduct of Atossa's business affairs. Because of his senior position, Quay knew the adverse non-public information about Atossa's misstatement of income and expenses and false financial statements.

117. As an officer and/or director of a publicly owned company, Defendant Quay had a duty to disseminate accurate and truthful information with respect to Atossa's financial condition and results of operations, and to correct promptly any public statements issued by Atossa which had become materially false or misleading.

118. Because of his position of control and authority as a senior officer, Defendant Quay was able to, and did, control the contents of the various reports, press releases and public filings which Atossa disseminated in the marketplace during the Class Period concerning Atossa's results of operations. Throughout the Class Period, Defendant Quay exercised his power and authority to cause Atossa to engage in the wrongful acts complained of herein. Defendant Quay was a "controlling persons" of Atossa within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the unlawful conduct alleged which artificially inflated the market price

119. By reason of the above conduct, Defendant Quay is liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Atossa.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and,

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury in this action on all issues so triable.

Dated: October 19, 2017

**ZWERLING, SCHACHTER &
ZWERLING LLP**

s/ Dan Drachler
Dan Drachler (WSBA #27728)
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
(206) 223-2053 phone
(206) 343-9636 fax
ddrachler@zsز.com

Liaison Counsel for Lead Plaintiffs

POMERANTZ LLP

Jeremy A. Lieberman, *pro hac vice*
Marc I. Gross, *pro hac vice*
Michael J. Wernke, *pro hac vice*
600 Third Avenue, 20th Floor
New York, New York 10016
(212) 661-1100 phone
(212) 661-8665 fax

SECOND AMENDED CLASS ACTION
COMPLAINT
CASE NO: 13-cv-1836-RSM

jalieberman@pomlaw.com
lfportnoy@pomlaw.com
mjjwernke@pomlaw.com

and

Patrick V. Dahlstrom
10 South LaSalle Street, Suite 3505
Chicago, Illinois 60603
(312) 377-1181 phone
(312) 377-1184 fax
pdahlstrom@pomlaw.com

BLOCK & LEVITON LLP

Jeffrey C. Block, *pro hac vice*
Jacob A. Walker, *pro hac vice*
155 Federal Street, Suite 400
Boston, Massachusetts 02110
(617) 398-5600 phone
(617) 507-6020 fax
jeff@blockesq.com
jake@blockesq.com

Co-Lead Counsel for Lead Plaintiffs and the Class

**BRONSTEIN GEWIRTZ & GROSSMAN
LLP**

Peretz Bronstein
60 E. 42nd Street, Suite 4600
New York, New York 10165
Telephone: (212) 697-6484
Facsimile: (212) 697-7296
peretz@bgandg.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 19, 2017, the foregoing document was filed electronically using the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

By: s/ Dan Drachler
Dan Drachler (WSBA #27728)
ZWERLING, SCHACHTER &
ZWERLING, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101
Telephone: (206) 223-2053
Facsimile: (206) 343-9636
ddrachler@zsz.com

Liaison Counsel for Lead Plaintiffs

CERTIFICATE OF SERVICE
CASE NO: 13-cv-1836-RSM

Zwerling, Schachter & Zwerling, LLP
1904 Third Avenue, Suite 1030
Seattle, WA 98101-1170
Tel.: (206) 223-2053